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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,331	01/30/2001	Paul Alfred Dickinson	CARP-0085	5411

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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
1614	8

DATE MAILED: 03/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/647,331	Applicant(s) DICKINSON ET AL.	
	Examiner Clinton Ostrup	Art Unit 1614	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

P riod f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) *1-35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-37 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15 and 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the propellant", however, there is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane", however, there is insufficient antecedent basis for this limitation in the claim. Furthermore this appears to be an incomplete Markush type claim.

Claim 31 lacks antecedent basis because it describes a method for "preparing an aerosol composition according to any one of claims 1 to 24", however, claim 24 does not positively recite the composition as an aerosol.

Any remaining claims are rejected as depending on indefinite base claims.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-10, and 12-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Glaxo Group Limited **WO 96/19968**. Glaxo Group Limited **WO 96/19968** discloses a

pharmaceutical aerosol formulation for the administration of medicaments by inhalation comprising, a particulate medicament, at least one sugar, and a fluorocarbon or hydrogen containing chlorofluorocarbon propellant. See: abstract and page 1, line 30 – page 2, line 1. The reference teaches the specific medicaments of instant claims 18-20 and the specific propellants of instant claims 13-15. See: page 2, line 21 – page 5, line 14.

Glaxo Group Limited **WO 96/19968** describes the particulate medicament as having a diameter of less than 15 micrometers, preferably in the range of 1 to 10 micrometers, thus meeting the size limitations of claims 1, 5, 24, and 33. See: page 2, lines 10-20. Moreover, the reference teaches and claims a combination of medicaments which meet the specific limitations of instant claims 21-23. See: page 2, line 21 – page 4, line 11 claims 7-10 and claims 14-16. Furthermore, the reference teaches that proteins and peptides such as insulin and glucagon may be used as therapeutic agents, thus meeting the specific limitation of instant claim 17. See: page 3, lines 1-10.

Glaxo Group Limited **WO 96/19968** further describe the sugar as having a particle size of less than 100, including sizes of 70 and 20 microns as examples of particle sizes under 100 microns, which meets the specific limitations of claims 1, 2, 24, and 33. See: page 4, lines 17-25. Glaxo Group Limited **WO 96/19968** also describe the ratio of medicament to sugar as being between the range of 1:0.01 to 1:100, preferably 1:0.1 to 1:10, thus meeting the ranges as claimed instantly by claims 3-4. See: page 4, lines 11-16.

The reference teaches that the aerosols may contain surfactants, taste masking agents, buffers, antioxidants and chemical stabilizers, thus meeting the specific limitations of instant claim 12. See: page 5, line 30 – page 7, line 14. The sugars taught by the reference include lactose, sucrose, mannitol, and dextrose, thus meeting the carbohydrate limitation of instant claim 16. See: page 4, lines 17-25 and Examples 1-144.

Glaxo Group Limited **WO 96/19968** teaches aerosol metered dose inhaler formations and containers which meet the limitations of instant claims 25-28, 31-32 and using the compositions for respiratory disorders as claimed instantly in claims 34-35. See: page 3, lines 10-23 and page 9, line 24- page 10, line 26.

The Glaxo Group Limited **WO 96/19968** reference meets the limitations of instant claims 1-10 and 12-37 and therefore, clearly anticipates the instant invention. Although the Glaxo Group Limited WO 96/19968 does not specifically teach the Mohs hardness value, this is a physical property of lactose, thus a value that is inherent to the composition. Furthermore, the working examples of the instant application use lactose as a particulate material, therefore, it is reasonable to expect the lactose particulate material of **WO 96/19968** to have the same Mohs hardness value as claimed instantly.

Claim Rejections - 35 USC § 103

Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Glaxo Group Limited **WO 96/19968** as applied to claims 1-9, 12-37 above and further in view of Glaxo Group Limited **WO 95/24889** and Schultz et al., **WO 92/06675.**

Although the primary reference teaches a pharmaceutical aerosol formulation for the administration of medicaments by inhalation comprising, a particulate medicament, at least one sugar, and a fluorocarbon or hydrogen containing chlorofluorocarbon propellant, the primary reference lacks the amount of propellant as claimed instantly in claims 10.

Glaxo Group Limited **WO 95/2488** discloses inhalation compositions containing lactose pellets that may be spray dried, thus teaching lactose pellets with a low Mohs value. See: page 4, line30 – page 5, line13. Schultz et al., teach pharmaceutical aerosol formulations comprising beclomethasone 17,21 dipropionate and a propellant selected from the group consisting of the 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane or a mixture thereof, for treating asthma by pulmonary, buccal, or nasal administration. See page 1, lines 6-39 and abstract. The secondary reference teaches the propellant in amounts which overlap those of instant claim 10. See: page 3, line 34 – page 4, line 4.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the aerosolized composition of Glaxo Group Limited **WO 96/19968** by using sprayed dried lactose pellets as taught by Glaxo Group Limited **WO 95/24889** and adding the amounts of propellant as taught by Schultz et al., because of the reasonable expectation of obtaining an aerosolized respiratory disorder treatment formulation that is capable of delivering particulate medicaments to the lungs, mouth and nose using hydrofluorocarbons that are less destructive to the ozone than other propellants such as, chlorofluorocarbons.

Conclusi n

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1614

March 14, 2002

FREDERICK KRASS
PRIMARY EXAMINER
Group 1600